John E. Flaherty
Jonathan M. H. Short
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
T (973) 622-4444
F (973) 624-7070

Attorneys for all Plaintiffs

Of Counsel:
Eric J. Lobenfeld
Arlene L. Chow
Dillon Kim
Hogan Lovells US LLP
875 Third Avenue
New York, New York 10022
(212) 918-3000

Attorneys for all Plaintiffs

Philippe Y. Riesen
Hogan Lovells Horitsu Jimusho
Gaikokuho Kyodo Jigyo
15th Floor Daido Seimei
Kasumigaseki Building
1-4-2 Kasumigaseki
Chiyoda-ku, Tokyo 100-0013 Japan
(81) 3-5157-8200

Attorney for all Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs and Counterclaim-Defendants, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants and Counterclaim-Plaintiffs.	:	Civil Action No. 3:10-CV-01723-JAP-TJB **PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR RECONSIDERATION**

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PRELIMINARY STATEMENT

"[A] motion for reconsideration should not provide the parties with an opportunity for a second bite at the apple." *Church & Dwight Co. v. Abbott Labs.*, 545 F. Supp. 2d 447, 450 (D.N.J. 2008) (citation omitted). With their motion of October 19, 2011 ("Motion"), Defendants Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (together, "Zydus" or "Defendants"), try to do just that by raising the same arguments previously advanced in their claim construction briefing and at the *Markman* hearing. (*See* Memorandum of Law in Support of Defendants' Motion for Reconsideration of Claim Construction ("Def. Br."), Dkt. 116-1.) To the extent that Zydus argues "clear error," their showing does not come close to meeting that standard. Their request should be denied.

On October 5, 2011, after extensive briefing, expert reports and depositions, and a full *Markman* hearing, this Court issued its carefully considered claim construction opinion ("Opinion" (Dkt. 113)) construing terms in U.S. Patent No. 6,328,994 (the "'994 patent") and U.S. Patent No. 7,431,942 (the "'942 patent")[1]. Among other disputed terms, the Court construed "fine granules having an average particle diameter of 400 µm or less" from Claim 1 of the '994 patent to mean "fine granules up to and including the enteric coating layer having an average particle diameter of 400 µm (±10%) or less." (Opinion at 7.) Similarly, it construed the terms "wherein the average particle diameter of the fine granule is 300 to 400 µm" from Claim 2 of the '994 patent and "fine granules having an average particle diameter of 300 to 400 µm" from Claim 1 of the '942 patent to mean, in relevant part, granules with an average particle diameter of

[1] The parties also stipulated and the Court signed an Order (Dkt. 97) extending the claim construction ruling to the related patent U.S. Patent No. 7,875,292.

300 to 400 µm (±10%). (Opinion at 8, 10; '994 patent, claim 2; '942 patent, claim 1.)[2] In adopting Plaintiffs' proposed constructions, the Court concluded that when read in light of the specification, Claim 1 did not require a hard cut-off, but instead incorporated a "universally accepted" measurement variation of ±10%. (Opinion at 5-7.) The Court rejected a number of Defendants' arguments, made both in their briefing and at the claim construction hearing.

Those same arguments are raised again in Defendant's Motion for Reconsideration. The motion is an attempt to get a second bite of the apple and should be denied. Defendant does not establish any factual or legal justification to modify the constructions adopted in the Court's October 5th Order.

ARGUMENT

I. THE LEGAL STANDARD FOR MOTIONS FOR RECONSIDERATION

A motion for reconsideration is an "extraordinary remedy" that should be "granted only sparingly." *AstraZeneca Pharms. LP v. Handa Pharms., LLC*, Civil Action No. 08-3773, 2011 WL 601612, at*2 (D.N.J. Feb. 17, 2011) (Pisano, J.); *Church & Dwight*, 545 F. Supp. 2d at 449. Because such motions "place[] a heavy burden on the movant," they are "only appropriate when one of the following three grounds for relief is established: (1) an intervening change in the controlling law has occurred; (2) evidence not previously available has become available; or (3) it is necessary to correct a clear error of law or prevent manifest injustice." *AstraZeneca*, 2011 WL 601612, at *2 (citation omitted); *see also Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 251 (3d Cir. 2010).

[2] Throughout the parties' briefing and the Court's Opinion and Order, the parties have treated the construction of these three terms as depending on the same considerations. Because the reasoning applicable to one term applies to the other two, the remainder of this brief will, for the sake of simplicity, speak only in terms of Claim 1 of the '994 patent.

Importantly, "[a] motion for reconsideration is not an appeal." *Ciba-Geigy Corp. v. Alza Corp.*, Civil Action No. 91-5286, 1993 WL 90412, at *1 (D.N.J. Mar. 25, 1993). It is "improper" on a motion for reconsideration to "ask the Court to rethink what it had already thought through—rightly or wrongly." *FMC Corp. v. Guthery*, Civil Action No. 07-5409 (JAP), 2009 WL 2488148, at *3 (D.N.J. Aug. 11, 2009) (Pisano, J.) (quoting *Oritani Savings & Loan Ass'n v. Fidelity & Deposit Co.*, 744 F. Supp. 1311, 1314 (D.N.J. 1990), *rev'd on other grounds*, 989 F.2d 635 (3d. Cir. 1993)). Under Local Rule 7.1(i), "a motion for reconsideration will only succeed where 'dispositive factual matters or controlling decisions of law' were presented to the Court but not considered." *Ciba-Geigy*, 1993 WL 90412 at *1 (quoting *Pelham v. United States*, 661 F. Supp. 1063, 1065 (D.N.J. 1987)). A straightforward application of these well-established principles shows that Defendants' Motion must be denied.

II. RECONSIDERATION IS INAPPROPRIATE BECAUSE DEFENDANTS MERELY RECAPITULATE OLD ARGUMENTS

"Prior to reaching the merits of a motion for reconsideration, a court must determine whether the arguments are properly raised under the Local Rule." *E.g., Altay v. Tagayun*, Civil Action No. 06-2330 (JLL), 2006 WL 3827426, at *1 (D.N.J. Dec. 28, 2006). To justify reconsideration, a party "must show more than a disagreement with the Court's decision." *FMC Corp.*, 2009 WL 2488148 at *1 (quoting *G-69 v. Degnan*, 748 F. Supp. 274, 275 (D.N.J. 1990)). "[A] mere recapitulation of the cases and arguments considered by the court before rendering its original decision" does not "fulfill the burden of the moving party." *AstraZeneca*, 2011 WL 601612 at *2 (quotation and citation omitted); *FMC Corp.*, 2009 WL 2488148 at *1.

In this case, Defendants argue (1) that the intrinsic evidence does not support construing "fine granules" to mean particles "having an average particle diameter of 400 µm (±10%) or less" and (2) that the Court misconstrued the significance of the U.S. Pharmacopeia in reaching the

±10% figure. Defendants admit each of these arguments was already raised during the *Markman* hearing and in the extensive briefing that preceded the Court's October 5th Order. (*See* Def. Br. at 4-5 & nn.3-4 (expressly recapitulating arguments made "[i]n their opening claim construction brief and the hearing before this Court"); *id.* at 8-9 & nn.8-9 (advancing, for the second time, "Zydus' *Markman* hearing argument"); *id.* at 13 & n.13 (repeating arguments made "by Zydus during the *Markman* hearing")). Defendants' Memorandum thus provides conclusive evidence that this case is not a proper candidate for reconsideration. *See, e.g., Hoffman-La Roche v. Roxane Labs., Inc.*, Civil Action No. 09-6335 (WJM), 2011 WL 2446600, at *2 (D.N.J. June 16, 2011) ("A court must deny a motion that simply rehashes the claims already considered.") (internal quotations and citations omitted); *Ciba-Geigy*, 1993 WL 90412 at *3 ("The Court characterizes defendants' statements as mere rehashing of arguments already submitted, received and evaluated. . . . This Court shall not serve as its own appellate panel."); *see also AstraZeneca*, 2011 WL 601612, at *2; *FMC Corp.*, 2009 WL 2488148 at *1. For that reason alone, Defendants' Motion should be denied.[3]

Recognizing that motions for reconsideration of *Markman* orders are unlikely to do anything more than re-litigate issues on which the movant has already lost, this Court has routinely denied such requests. *See, e.g., Lonza Inc. v. Nalco Co.*, Civil Action No. 09-4635 (JLL), 2011 WL 4592396, at *2-3 (D.N.J. Sept. 29, 2011) (denying motion for reconsideration of *Markman* ruling where movant relied on cases and arguments advanced before the court because such motions are "not an opportunity to now re-litigate issues already considered and decided by

[3] To the extent that Defendants' Motion raises new arguments, that is another reason to deny reconsideration. *See, e.g., Leja v. Schmidt Mfg., Inc.*, 743 F. Supp. 2d 444, 456 (D.N.J. 2010) ("[A] motion for reconsideration may not be premised on legal theories that could have been adjudicated or evidence which was available but not presented prior to the earlier ruling."); *Church & Dwight*, 545 F. Supp. 2d at 450 ("Generally, the moving party is not entitled to raise new arguments that could have been addressed in the original moving and responsive papers.").

the court"); *AstraZeneca*, 2011 WL 601612 at *2 (denying reconsideration where defendant "offer[ed] nothing more than recapitulation of the cases and arguments considered by the [C]ourt before rendering its original decision.") (alteration in original) (internal quotation marks omitted).[4] Defendants here have not identified *any* dispositive facts or law that were put before the Court and not considered. The Motion should be denied.

III. THERE IS NO MANIFEST INJUSTICE AND DEFENDANTS' SUBSTANTIVE ARGUMENTS ARE WITHOUT MERIT

A. Clear error is a demanding standard.

Defendants assert that "this motion … is necessary to correct a clear error of law and fact to prevent manifest injustice." (Def. Br. at 3.) Under New Jersey law, "[a] decision suffers from 'clear error' only if the record cannot support the findings that led to that ruling." *Leja v. Schmidt Mfg., Inc.*, 743 F. Supp. 2d 444, 456 (D.N.J. 2010) (denying reconsideration). "Thus, a party must do more than allege that portions of a ruling were erroneous in order to obtain reconsideration of that ruling; it must demonstrate that (1) the holdings on which it bases its request were without support in the record, or (2) would result in 'manifest injustice' if not addressed." *Id.* Defendants cannot make such a showing. The record not only supports the Court's October 5th Order, it undercuts each of the arguments made in Defendants' Motion.

[4] *See also Schering Corp. v. Mylan Pharms., Inc.*, Civil Action No. 09-6383, 2011 WL 3328940, at *1 (D.N.J. Aug. 1, 2011) (rejecting defendant's argument "that the Court misinterpreted the intrinsic and extrinsic evidence" in construing the disputed terms and denying the motion for reconsideration where defendant "simply resubmit[ed] arguments that were already presented to this Court, in an apparent attempt to argue that the Court's claim constructions were made under a clear error of law"); *Aventis Pharms., Inc. v. Barr Labs., Inc.*, Civil Action No. 01-3627, 2004 WL 3142511, at *7 (D.N.J. Dec. 20, 2004) ("This Court finds there have been no intervening changes in controlling law, no evidence made available that was not previously available, nor a clear error of law in the October 22, 2004 opinion of the Court. Plaintiffs merely seek a revisitation of the cases and arguments already considered by this Court before rendering it's earlier decision, and, as a result, fail to carry the burden of a moving party on a motion for reargument.").

B. Plaintiffs have established that "400 µm or less" means 400 µm (±10%) or less.

In its October 5th Order, the Court recognized the '994 patent's specification shows that the term "fine granules having an average particle diameter of 400 µm or less" is not precise, for it clearly and consistently correlates "400 µm or less" with "about 400 µm or less." (Opinion at 5-6; '994 patent, col. 2, ll. 18-21; col. 5, ll. 57-63.) Defendants are wrong to assert that "the Court erred by overlooking the primacy of intrinsic evidence with respect to claim construction" and based its decision "solely on disfavored extrinsic expert testimony." (Def. Br. at 2, 5.)

Defendants appear now to have abandoned their "hard cut-off" argument in favor of one that concedes that "400 µm or less" incorporates a standard of error, but one to be determined not by reference to the specification but by reference to extrinsic evidence. (*Compare* Dkt. 69 at 10 *with* Def. Br. at 2, 12-14.)[5]

Pharmaceutical formulation art in turn recognizes that the relevant standard of error for the measurement of particle sizes is ±10%. The '994 patent teaches that "[average particle diameter] can be measured by, for example, a laser diffraction particle distribution measurement method." ('994 patent, col. 5, ll. 46-47; *see also* Opinion at 6.) The U.S. Pharmacopeia ("USP") is the official public standard-setting authority for medicines and healthcare products manufactured in the United States. Defendants' expert concedes it is the "primary reference" for particle size measurement. (Meyer-Stout Dep. Tr. 30:9-19; 87:16-88:5 (Dkt. 90, Ex. 24).) The USP defines the standard of error for light diffraction as ±10%. (Byrn Decl. (Dkt. 70) ¶¶ 28-30; Ex. 5, USP at 7.) Peer-reviewed literature and experts in the art agree. (Byrn Decl. (Dkt. 70) ¶30 & Ex. 6.) Thus, as the Court found, on the basis of a comprehensive and fully developed

[5] This new argument could have been raised before and therefore is improper on a motion for reconsideration

factual record, "400 µm or less," as understood by a person of skill in the art, means an average particle diameter of 400 µm (±10%) or less.

C. Defendants' arguments do not justify revising the Court's claim construction order.

The arguments advanced by Defendants in their motion for reconsideration, which were made and rejected during the *Markman* hearing, do nothing to counter this conclusion. Defendants improper new arguments also do not justify revising the claim construction.

First, Defendants argue that construing "400 µm or less" as 400 µm (±10%) or less allows the claim to read on disavowed and mutually exclusive prior art, namely large particles. (Def. Br. at 4-8.) This is not so. As an initial matter, Defendants' argument is wholly undermined by their own proposed revised claim construction, which recognizes that "400 µm or less" is not precise and incorporates a variance of ±3%. (Def. Br. at 1, 15.) The fact that each of the "problems" identified in Defendants' brief applies equally to their proposed new definition, provides another reason to reject Defendants new arguments.

Defendants arguments also lack legal and factual support. As current Federal Circuit case law cited in Defendants' brief makes clear, "[t]o disavow claim scope, the specification must contain expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1306 (Fed. Cir. 2011) (internal quotation and citation omitted); *see also Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1315 (Fed. Cir. 2010) (same) *Epistar Corp. v. Int'l Trade Comm'n,* 566 F.3d 1321, 1335 (Fed. Cir. 2009) (same); *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1357-58 (Fed. Cir. 2006) (same). Thus, as a general rule, "statements about the difficulties and failures in the prior art, without more, do not act to disclaim claim scope." *Retractable Techs.*, 653 F.3d at 1306 (citing *Spine Solutions,* 620 F.3d at 1315; *see also,*

e.g., *Epistar*, 566 F.3d at 1336 ("[D]isparaging comments alone do not necessarily show a manifest or express disavowal of the criticized subject matter.").

In distinguishing fine granules that do "not impart roughness in the mouth" and "can easily be administered without discomfort" from "[g]ranules having a large particle diameter" that "produce a feeling of roughness in the mouth," the '994 patent does not disavow particles having a diameter of 400 μm ±10%, and thus encompasses particles with a diameter of up to 440 μm. ('994 patent, col. 2, ll. 16-18; col. 37, ll. 20-25.) Claim 1 and the specification of the '994 patent are clear that "fine granules" include those with an average particle diameter of 400 μm. (*E.g.*, '994 patent, col. 3, ll. 15-16; col. 37, ll. 44-45.) Thus, Defendants assertions that there is a "clear disavowal of particles with an average particle diameter of 400 μm" and that "fine granules" and "large granules" were precisely and "mutually exclusively defined in the specification" are flat-out wrong. (Def. Br. at 2, 7.)

The term "fine granules having an average particle diameter of 400 μm or less" is not precise and incorporates a reasonable standard of error. This would be recognized by those skilled in the art. There is no basis for concluding that allegedly disparaging comments about large particles prevent the '994 patent from reading on particles with an average diameter of up to 440 μm or that the distinction between fine and large particles somehow imposes a hard cut-off of 400 μm. *See Retractable Techs.*, 653 F.3d at 1306; *Epistar*, 566 F.3d at 1336; *Spine Solutions*, 620 F.3d at 1315. Indeed, the user of an orally disintegrable tablet would be unlikely to notice the difference between particles with average diameters of 400 μm and 440 μm. (*See* May 26, 2011 Markman Hearing Transcript at 14-15.) Accordingly, the distinction between fine and large granules cannot be used to impose a hard cut-off at 400 μm.

Second, Defendants repeat their "*Markman* hearing argument that the 'average particle diameter' of the fine granules cannot be as high as 440 µm because that would place the average particle diameter substantially above the maximum allowable particle diameter permitted by the specification." (Def. Br. at 8-9.) But such a result is only possible if the patent is read in a contradictory fashion designed to create internal inconsistencies. Just as "400 µm or less" incorporates a variation ±10%, so too does the maximum particle size of "425 µm or less." Once that is recognized, Defendants' argument, which the Court implicitly rejected in its October 5th Order, fails.

Finally, having conceded "400 µm or less" is not precise, that it incorporates a standard of error, and that the USP is the authoritative source for determining that standard of error, Defendants now argue that the appropriate standard of error is 3%. (Def. Br. at 12-14.) This argument is untimely and wrong. First, at no point in its *Markman* briefs or expert report did Defendants make such an argument. Second, Plaintiffs' unrebutted expert testimony, based on the USP and peer-reviewed publications authored by the Product Quality Research Institute, establishes that "[w]hen using… laser diffraction particle distribution measurement method, . . . a deviation of 10% for any particle size measurement is universally accepted." (Byrn Decl. (Dkt. 70) ¶¶ 28-30.) Third, the 3% variability that Defendants now advocate comes from the "Qualification" section of the USP and concerns "qualification validation . . . made with any certified or standard reference material." (Byrn Decl. (Dkt. 70), Ex. 5, USP at 7-8.) That section addresses "confirm[ing] the correct operation of the instrument." (Byrn Decl. (Dkt. 70), Ex. 5, USP at 8.) Needless to say, that section does not speak to the issue at hand—measuring particle diameter in a pharmaceutical formulation. As the Court has already found, such measurements allow for a variation of ±10%.

Because Defendants are unable to show clear error of law or fact, the Motion must be denied.

CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court deny Defendants' Motion for Reconsideration and reaffirm the claim constructions entered by the October 5th Order. Reconsideration is inappropriate because Defendants merely recapitulate old arguments. Defendants admit each of their arguments was already raised during the *Markman* hearing and in the extensive briefing that preceded the Court's October 5th Order and have not identified *any* dispositive facts or law that were put before the Court and not considered. Furthermore, Defendants cannot make a showing that the Court's claim construction was a clear error of law. On the basis of a comprehensive and fully developed factual record, this Court construed "400 µm or less" to mean an average particle diameter of 400 µm (±10%) or less. The Court already considered—and rejected—Zydus's arguments advocating a different construction. Zydus fails to justify why reconsideration of the Court's claim construction is warranted.

Respectfully submitted,

Dated: November 7, 2011

By: *s/John E. Flaherty*
John E. Flaherty
Jonathan M.H. Short
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for all Plaintiffs

OF COUNSEL:
Eric J. Lobenfeld
Arlene L. Chow
Dillon Kim
Hogan Lovells US LLP
875 Third Avenue
New York, New York 10022
(212) 918-3000

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Hogan Lovells Horitsu Jimusho
Gaikokuho Kyodo Jigyo
15th Floor Daido Seimei
Kasumigaseki Building
1-4-2 Kasumigaseki
Chiyoda-ku, Tokyo 100-0013 Japan
(81) 3-5157-8200

Attorneys for all Plaintiffs

CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR RECONSIDERATION were caused to be served on November 7, 2011 via email and the ECF system upon all counsel of record.

By: *s/John E. Flaherty*
John E. Flaherty